



Health Effects Institute

23 April, 1999

955 Massachusetts Avenue
Cambridge, MA 02139
(617) 876-6700
FAX (617) 876-6709
<http://www.healtheffects.org>

Joan E. Denton, Ph.D.
Director
Office of Environmental Health Hazard Assessment
California Environmental Protection Agency
301 Capitol Mall, Rm. 205
Sacramento, CA 95814-4308

OFFICE OF ENVIRONMENTAL HEALTH
HAZARD ASSESSMENT
Received

APR 26 1999

Sacramento

Joan
Dear Dr. Denton:

Thank you for your letter of April 14, 1999 concerning the Health Effect Institute's (HEI) diesel epidemiology report and workshop.

HEI and its Diesel Epidemiology Expert Panel have, from the beginning of this project, sought and benefitted from the input of experts from OEIHA, other risk assessment agencies, researchers, and scientists from industry and environmental organizations. On a number of occasions - the first workshop last Spring, the broad-based peer review of the draft, opportunities for OEIHA and others to discuss with the panel and its members the details and draft conclusions of its efforts, the workshop we held at Stone Mountain, and Dr. Dawson's latest comments (which we received earlier this month and immediately circulated to the full Panel) - the Panel has heard from and responded to many thoughtful comments in its deliberations. As a result, the document that the Panel is working on completing today is different from, and substantially better than, the draft that your staff and others were asked to peer review in January.

The Panel also understood, from the outset, that it was not charged to repeat nor evaluate the broader risk assessments conducted by OEIHA, NIEHS/NTP, U.S. EPA, WHO, and IARC, all of which have found, based on reviews of the broader epidemiologic and toxicologic evidence, that diesel exhaust is a probable human carcinogen. They understood as well that based on these findings the California Air Resources Board went forward last fall to designate diesel exhaust particulate matter as a Toxic Air Contaminant.

The Panel's charge, rather, was to examine more closely one element of risk assessment - the development of quantitative estimates of risk - and to determine what additional research is necessary to improve our ability to make such estimates. To this end, the panel examined in detail two sets of studies - of railroad workers and teamsters - that have the best available exposure and health information and have been relied on most for quantitative risk estimates. Their analysis and review was designed solely to

April 23, 1999 Page 2

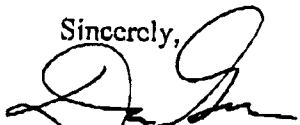
understand the strengths and weaknesses of these existing studies as they relate to quantitative risk assessment in order to determine whether future research on these populations, or on new populations, could improve our ability to quantify the risks for diesel exhaust.

One comment that you made about the January draft, and that we heard from many other reviewers as well, was about the seeming impossibility for any study to meet the "criteria for selection of epidemiology studies to be used for quantitative risk assessment" contained in the first draft. The Panel, who as practicing epidemiologists, exposure experts, and biostatisticians are the first people to recognize that there is no such thing as a perfect epidemiology study, had never intended to set up such unrealistic criteria all to be met in the conduct of a single study. Rather their intention was and is to see these guidelines as a framework of epidemiologic principles for systematically assessing strengths and weaknesses of the studies for quantitative risk assessment, with the understanding that any ultimate risk assessment has to be based on an assessment of all of the available literature rather than a specific study.

Finally, but by no means least importantly, we are acutely sensitive to the possibility that, given the nature of our scientific work and our efforts to design it to best inform future public decisions, any publication can be misinterpreted or misquoted. We are particularly concerned that some may already be starting to distribute "findings" of this HEI effort even before the final report has been completed, reviewed, and approved by HEI and we will be working to minimize the chance that these premature interpretations continue. As would normally be the case we plan to provide you, as well as other regulatory agencies and interested parties, with briefings on the final report when it is approved, and prior to broader public release.

We appreciate your continued interest in the work of HEI, welcome your comments, and look forward to working with you to advance the science of understanding risk. Please do not hesitate to call if you have any questions.

Sincerely,



Daniel S. Greenbaum
President

cc: Dr. Alan Lloyd, Chair
CARB